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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,980	01/29/2004	Itzhak Bentwich	050992.0201.02USCP	1979
37808 7590 05/28/2009 ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112				
EXAMINER				
ANGELL, JON E				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
05/28/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/707,980

**Applicant(s)**

BENTWICH, ITZHAK

**Examiner**

J. E. Angell

**Art Unit**

1635

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69-72, 89, 92 and 93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-72, 89, 92 and 93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### DETAILED ACTION

The amendment filed 3/12/09 is acknowledged and has been entered.

Claims 69-72, 89, 92, 93 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

#### *35 USC § 112, first paragraph*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 69, 70, 89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

*If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).*

MPEP §2163.02 teaches that:

*Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.*

MPEP §2163.06 further notes:

*When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Claims 69 and 89 encompass an isolated nucleic acid consisting of 19 to 140 nucleotides. Applicants have asserted that support for this limitation can be found in Table 4, paragraph 46. However, Table 4 and paragraph 46 do not provide support for the entire range of the claimed molecules that are 19-140 nucleotides in length. For instance, paragraph 46 only provides support for oligonucleotides that are "about 19 to about 24 nucleotides in length". It is also noted that paragraph 45 discloses that the oligonucleotides could be 50-140 nucleotides in length. However, neither about 19 to about 24 or 50-140 provide support for the entire range that is now claimed. Accordingly, the disclosure does not provide the required support for the instant claims. Claim 70 is a dependent claim that also encompasses these limitations; therefore, claim 70 is rejected for the same reasons.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 69, 70, 89 are also rejected under 35 U.S.C. 112, first paragraph, as

containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claims 69-72, 89, 92, 93 are also rejected under 35 U.S.C. 112, first paragraph because the claims appear to encompass sequences which are different from the disclosed sequences, but which have not been adequately described in the specification.

For instance, in their broadest embodiments, the claims encompass isolated nucleotide sequences that are 140 nucleotides in length but comprise only 19 consecutive nucleotides of SEQ ID NO: 142700, 140670, 140732, 2 or 9, wherein the 19 consecutive nucleotides can be ANY 19 consecutive nucleotides of the indicated sequences. As such, the claims encompass oligonucleotides wherein less than 15% of the nucleotides of the oligonucleotides are actually defined (note:  $19/140=0.136$ ). Thus, the claims encompass an extremely large genus of oligonucleotides, considering every possible oligonucleotide that meets the structural limitations of the claims. The specification describes the oligonucleotides of the claims as being related to micro-RNAs (miRNA) such as by actually being a miRNA or a precursor thereof. Accordingly, the function of the claimed oligonucleotides is as a miRNA or a precursor molecule which could be processed into a functional miRNA.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In the instant case, Applicants have not provided a description of the claimed molecules such that one of skill in the art would be able to identify which molecules had miRNA activity or which could be a precursor that is processed into a functional miRNA without performing additional experimentation.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

As discussed above, the skilled artisan cannot envision the detailed chemical structure of molecules encompassed by the claims which would have the asserted function and which molecules would not; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acid sequences encompassed by the claims, other than those expressly disclosed which represent variant nucleic acid sequences which have the desired

function. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Therefore, only isolated nucleic acids encoding the amino acid sequence set forth in SEQ ID NO: 142700, SEQ ID NO: 140732, SEQ ID NO: 140670, SEQ ID NO: 2 and SEQ ID NO: 9 meet the written description provision of 35 U.S.C. §112, first paragraph. Thus, applicant has express possession of only 5 specific sequences of a genus which comprises an enormous number of different possibilities.

### ***Response to Arguments***

3. Applicant's arguments have been fully considered and, in view of the amendment to the claims, are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made for the reasons set forth herein.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/  
Primary Examiner, Art Unit 1635